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March 20, 2015

Dr. Karen DeSalvo
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services

RE: A Shared Nationwide Interoperability Roadmap Draft Version 1.0

Dear Dr. DeSalvo,

On behalf of the American Immunization Registry Association (AIRA) we are pleased to submit comments on **Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap Draft Version 1.0**. As a member organization for Immunization Information System (IIS) programs and partners, these comments represent a broad perspective on federal actions that impact immunization programs across the country. We are committed to supporting ONC's process to coordinate efforts to protect and improve our nation's health with interoperable electronic health information.

We greatly appreciate that the Interoperability Roadmap is inclusive of public health agencies, and the critical role they play in exchanging data throughout the health care system. Public health agencies are front and center in building electronic data exchanges that meaningfully improve the entire population's health. This is particularly true in the area of immunizations; IIS are a critical link in the consolidation of health records and the delivery of clinical decision support. We appreciate that this plan recognizes and supports the critical role that public health systems such as IIS provide in standards-based information exchange.

AIRA's comments are presented on the following pages, organized by page number and section within the Roadmap. Please contact Rebecca Coyle, AIRA's Executive Director, with any questions: coyler@immregistries.org.

AIRA appreciates the work and vision of ONC in convening agencies and partners to develop this Roadmap. We look forward to its implementation across the healthcare ecosystem, and will support our members and partners in achieving its goals.

Sincerely,

Rebecca Coyle MEd, Executive Director
American Immunization Registry Association (AIRA)

Comments on the Interoperability Roadmap Draft Version 1.0

By: The American Immunization Registry Association (AIRA)

Section/ Page Number	Excerpt	Comment
Standards Development, <i>Table 1: Critical Actions for a Coordinated Governance Framework and Process for Nationwide Health Information Interoperability</i> Page 36	5) The coordinated governance process should use the standards evaluation process on an ongoing basis to coordinate the roll out of software and service changes so as not to disrupt established interoperability.	<p>AIRA appreciates the focus on not disrupting established interoperability, and, as a member organization representing establishments with hundreds of currently interoperating organizations and thousands of active interfaces, we would be happy to collaborate with ONC to ensure emerging standards do not interfere with current connections.</p> <p>In addition, it is critical that all federal efforts keep state- and jurisdiction-level legislative/policy mandates and data needs in mind, and not disrupt current active data submission and query functions that support both clinical and public health.</p>
<i>Table 2: Critical Actions for a Supportive Business and Regulatory Environment that Encourages Interoperability B2. State Actions,</i> Page 44	<p>1) Call to action: All states should have an interoperability roadmap articulated in their health-related strategic plans (including their Annual Medicaid Health IT Plan).</p> <p>2) Call to action: All states should take appropriate steps to implement policies that are in alignment to the national, multi-stakeholder approach to coordinated governance for interoperability.</p>	<p>AIRA is taking steps to coordinate efforts and develop collective governance among its 64 Immunization Information Systems (IIS) CDC Immunization Awardees, most of which operate at a state level. Early efforts are focused on joint development, but will extend to collective approaches to standards adoption and testing processes. This is only across IIS, and does not extend to full state interoperability activities, but lessons learned here should have broader applicability.</p>
<i>Table 3: Critical Actions for Individuals That Are Empowered, Active Partners in the Health and Health Care,</i> Page 48	C2. Providers and technology developers supporting individual empowerment	<p>Although IIS support consumer access to data, standards are needed to ensure uniform authentication and authorization for on demand record requests.</p> <p>In addition, standards will need to be in place to protect the integrity of the</p>



		clinical data as individuals are empowered to contribute as needed to their health information. Whenever possible, corrections should be made “upstream” (i.e., in a patient’s EHR) so that the correct information can flow into other records (i.e., an IIS).
Basic Choice v. Granular Choice, Page 65	<p>“Basic choice” is the choice an individual makes about the use and disclosure of their health information generally, including electronic exchange of health information that is not subject to heightened use and disclosure restrictions under state or federal law.</p> <p>“Granular choice” refers to the choice an individual makes to share specific types of information, including (1) information that fits into categories to which, by law, protections in addition to HIPAA apply; (2) the choice afforded an individual based on their age; and (3) the choice to share health information by specific provider or payer types.</p>	<p>Although we understand the need to keep control in the hands of the consumer, it is important to recognize that if granular choice extended to the consumer being able to choose, for example, which immunizations should be shared and which should not, this would create significant operational barriers to IIS-EHR data exchange. Particularly in public health, the value of granular choice should always be weighed against the cost and complexity of developing, tracking and auditing those granular options.</p> <p>It is also important to consider that there may be state policies or legislation that impact what an IIS may be required to maintain. Consumer may be unable to opt out of requirements based on local laws. Federal approaches should be mindful to avoid potential conflicts.</p>
Certification and Testing to Support Adoption and Optimization of Health IT Products and Services, Page 75	<p>A diverse and complementary set of certification and testing programs will need to be in place to achieve a nationwide learning health system.</p> <p>Certification in support of a learning health system should be specific and focused on the areas that have the greatest impact on interoperability.</p>	<p>AIRA and the IIS community are currently launching testing processes to validate uniform adoption of messaging and transport standards to support interoperability.</p> <p>Care should be taken to ensure that any certification or testing process is detailed and applied enough to actually accelerate and support interoperability; in other words, the testing itself should lead to modifications that support “meaningful” interoperability.</p>
Consistent Data Formats and Semantics,	Several vocabulary and terminology standards are already adopted by ONC in regulation and are required in	Although there may be a desire to consolidate or simplify the number of value sets or codesets in use across

<p>Page 79</p>	<p>the 2014 CEHRT definition and subsequently meaningful use stage 2⁵⁷. This includes, but is not limited to: Systematized Nomenclature of Medicine-Clinical Terms (SNOMED CT) for problems or conditions, RxNorm for medications and medication allergies, or Logical Observation Identifiers Names and Codes (LOINC) for laboratory tests and CVX for immunizations.</p>	<p>the health care ecosystem, it is important to consider the specificity of specific domains such as Immunizations, and AIRA supports the continued inclusion of CVX as a vocabulary standard.</p>
<p>Consistent Data Formats and Semantics, Page 80</p>	<p>Standards Development Organizations (SDOs) are primarily responsible for developing, curating and maintaining all of the standards mentioned above as well as any accompanying information models. These organizations include, but are not limited to: Health Level 7 (HL7), the National Council for Prescription Drug Plans (NCPDP), Integrating the Healthcare Enterprise (IHE), Clinical Data Interchange Standards Consortium (CDISC), Regenstrief Institute, IHTSDO, National Library of Medicine (NLM) and the National Center for Health Statistics under CDC. In addition to publishing standards, these organizations also create profiles or implementation specifications/guides that provide additional implementation instruction to developers based on the particular purpose for which the standard is intended to be used. For instance, the HL7 2.5.1 standard is a content standard for which several different implementation guides have been created to address specific purposes ranging from lab result receipt to immunization submission.</p>	<p>AIRA appreciates that the roadmap acknowledges the work of HL7 and the Immunization Information System (IIS) community in crafting and refining standards for use of HL7 2.5.1 in IIS messaging. This is a successful and proven messaging standard that is fully operational among IIS and Electronic Health Record (EHR) partners.</p>



<p>Consistent, Secure Transport Techniques, Page 90</p>	<p>L2. Send – 1) Public health agencies should converge on the use of standardized web services to support data submission as well as data query from registries and other systems. 2) Providers (including hospitals, ambulatory providers, long-term care centers and behavioral health providers) should adopt and use DIRECT to reach critical mass.</p>	<p>The IIS community has adopted and implemented SOAP/Web Services as its transport standard, and we support its continued implementation. We are concerned with DIRECT as a standard because it does not support real-time bidirectional data exchange, a use case critical for IIS-EHR interoperability.</p>
<p>Consistent, Secure Transport Techniques, Page 90</p>	<p>L3. Receive and Find – 4) Health IT developers should widely implement national standards for query. 5) Health IT developers should widely implement national standards for publish/subscribe. 6) Health IT developers should implement national standards for RESTful web services as they are available.</p>	<p>Although we agree with the recommendation to implement national standards for query, AIRA would support SOAP/Web Services over RESTful web services for the following reasons:</p> <ol style="list-style-type: none"> 1) SOAP is already broadly implemented and proven within IIS-EHR interfaces 2) The Microsoft .net environment, used heavily among EHR vendors, has SOAP support built-in 3) The SOAP interface can be used to deliver any standardized message <p>AIRA strongly encourages that ONC request broad input from Public Health and the EHR vendor community on the inclusion of SOAP vs. REST as a web services standard. Ideally, only one preferred web service standard should be recommended and supported.</p>
<p>Accurate Individual Data Matching, Pages 90-95</p>	<p>Accurate identity matching: Whether aggregated in a repository or linked "just in time," health information from disparate sources must be accurately matched to prevent information fragmentation and erroneous consolidation....</p>	<p>AIRA and the IIS community are pleased to see a section in the Roadmap devoted to patient matching. The IIS community, in collaboration with CDC, has invested significant time and expertise exploring these issues, and would like to share this work to date, while also participating in future efforts to develop standards and tools in this arena. Resources developed to date can be found at:</p>



		<p>http://www.cdc.gov/vaccines/programs/iis/technical-guidance/deduplication.html</p> <p>In particular, AIRA would be interested in collaborating on methods to test algorithms for accurate matching.</p> <p>AIRA also supports the exploration of standards and best practices for information level matching/deduplication (e.g., in the consolidation of multiple reports for one single immunization administered.</p>
<p>Accurate Individual Data Matching Page 93</p>	<p>The data elements listed below are a starting point for standardization:</p> <ul style="list-style-type: none"> • First/Given Name • Current Last/Family Name • Previous Last/Family Name • Middle/Second Given Name (includes middle initial) • Suffix • Date of Birth • Current Address (street address, city, state, ZIP code) • Historical Address (street address, city, state, ZIP code) • Current Phone Number (if more than one is present in the patient record, all should be sent) • Historical Phone Number • Gender 	<p>When considering minimum recommended data elements for identity matching, it will be important to look at all of the different types of systems on the “care continuum” and not just EHRs, IIS or other systems and the data elements they are currently expected to capture vs. what would be useful for identity matching.</p> <p>A report of the IIS community’s exploration and evaluation of these elements can be found at: http://www.cdc.gov/vaccines/programs/iis/interop-proj/downloads/de-duplication.pdf</p>
<p>Reliable Resource Location, Page 96</p>	<p>Resource location is the electronic means for discovering participants of a learning health system and the services they provide for sharing or accessing data. A learning health system will include a complex and expanding ecosystem of participants and services, using an evolving set of standards. It will require a means to electronically and conveniently locate participants of interest and services that provide the needed data resources.</p>	<p>As a consolidator of records, an IIS can be a significant contributor in strategies to locate participants and services that provide needed data resources.</p>



<p>Measuring the Flow and Use of Interoperable Information, Contextual Information, Page 108</p>	<p>Measuring perceived accuracy, reliability, trustworthiness and utility of information exchanged will help understand variation in use of data. Additionally, information from the end user perspective on barriers to exchange and interoperability may ensure early identification of issues and addressing of concerns.</p>	<p>As systems that consolidate data from thousands of sources that may vary in reliability/quality, IIS can share lessons learned on algorithms to select the “best report” and other metrics to measure quality. We would also be interested in participating in future efforts to design more complex methods to ensure data quality.</p>
<p>Appendix H: Priority Interoperability Use Cases, Page 163</p>	<p>Coordinated governance processes should help refine and prioritize this list to then prioritize development of technical standards, policies and implementation specifications.</p>	<p>The AIRA community strongly encourages the prioritization of the following use cases: 2) Clinical settings and public health are connected through bi-directional interfaces that enable seamless reporting to public health departments and seamless feedback and decision support from public health to clinical providers. 27) Data for disease surveillance, immunization tracking and other public health reporting are exchanged automatically. 29) Query-based exchange should support impromptu patient visits in all settings.</p> <p>AIRA also encourages the recognition of these use cases as high priority: 1) Public health agencies routinely use data derived from standards -based connections with HIEs and EHRs and uses it to plan investments in public health activities. 35) Individuals have electronic access to an aggregated view of their health information including their immunization history.</p> <p>Finally, we encourage ONC to request input and comment from the provider community on the following use case: 8) CEHRT should be required to provide standardized data export and import capabilities to enable providers to change software vendors.</p>